Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

A comparative study of Tramadol and Ondansetron in controlling pain and shivering in pregnant women candidate for cesarean section

Protocol summary

Study aim
Comparison the effect of Tramadol and Ondansetron in controlling pain and shivering in pregnant women candidate for cesarean section

Design
This three-phase clinical trial, with parallel groups, randomized (using the allocation randomization rule) is performed on 60 pregnant women candidates for elective cesarean section.

Settings and conduct
In this interventional study, 60 pregnant women candidates for elective cesarean section in Yas hospital are selected by convenience sampling.

Participants/Inclusion and exclusion criteria
Inclusion criteria include all pregnant women who are candidates for elective cesarean section with spinal anesthesia. Exclusion criteria: patients with sensitivity to Tramadol or Ondansetron, Emergency cesarean section, and Contraindications to spinal anesthesia.

Intervention groups
After performing spinal anesthesia for the patient, for the intervention, 4 mg of Ondansetron is injected by the anesthesiologist as an intravenous bolus and for the control group, ۰.۵ mg/kg of Tramadol is injected by the anesthesiologist as an intravenous bolus.

Main outcome variables
The patient's shivering and pain after the surgery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220620055225N3**
Registration date: **2023-06-26, 1402/04/05**
Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**
Update count: **0**

Registration date
2023-06-26, 1402/04/05

Registrant information
Name
Khadijeh Adabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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kh_adabi@sina.tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-06, 1402/04/15
Expected recruitment end date
2023-11-21, 1402/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of Tramadol and Ondansetron in controlling pain and shivering in pregnant women candidate for cesarean section

Public title
The controlling pain and shivering in pregnant women candidate for cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

All pregnant women are candidates for elective cesarean section with spinal anesthesia

Exclusion criteria:

Sensitivity to Tramadol or Ondansetron Emergency cesarean section Contraindications to spinal anesthesia include intracranial space lesions, systemic or spinal anesthesia puncture site infection, and coagulation disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 30 letters A and 30 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (intervention) or B (control) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed double-blind, the participants and the researcher do not know the type of treatment. For each patient, the appropriate study drug was prepared and diluted (clear and transparent solution) to a volume of 4 ml (in a 5 ml syringe).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Pour Sina Ave., Qods Blvd.

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Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.478

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O75.82

ICD-10 code description

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description

The patient's shivering

Timepoint

Once, after delivery

Method of measurement

Using Tsai and Chu criteria

2

Description

The amount of patient's pain

Timepoint

Once, after delivery

Method of measurement

Using VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After performing spinal anesthesia for the patient, 4 mg of Ondansetron is injected by the anesthesiologist as an intravenous bolus.

Category

Treatment - Drugs

2

Description

Control group: After performing spinal anesthesia for the patient, ۰.۵ mg/kg of Tramadol is injected by the anesthesiologist as an intravenous bolus.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Khadijeh Adabi

Street address

Yas hospital, Next to the Sarv St., North Nejatollahi Str., Karim khan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi

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Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Khadijeh Adabi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The anonymous study data is potentially shareable.
When the data will become available and for how long
After the manuscript is published.
To whom data/document is available
No limitations.
Under which criteria data/document could be used
The data is only available to the project manager, Dr. Khadijeh Adabi, and any analysis must be done with her opinion.
From where data/document is obtainable
Dr. Khadijeh Adabi
What processes are involved for a request to access data/document
Any request must be sent by e-mail with its proposal to Dr. Khadijeh Adabi.
Comments